

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
REQUEST FOR FILING NATIONAL PHASE OF
PCT APPLICATION UNDER 35 U.S.C. 371 AND 37 CFR 1.494 OR 1.495

To: Hon. Commissioner of Patents
Washington, D.C. 20231



00909

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)

Atty Dkt: P 279277 /2892USAS/VO
M# /Client Ref.

From: Pillsbury Winthrop LLP, IP Group:

Date: March 30, 2001

This is a **REQUEST** for **FILING** a PCT/USA National Phase Application based on:

- | | | |
|--|---|---|
| <p>1. International Application</p> <p><u>PCT/EP99/07692</u></p> <p><u>fr</u> country code</p> | <p>2. International Filing Date</p> <p><u>13</u> <u>October</u> <u>1999</u></p> <p>Day MONTH Year</p> | <p>3. Earliest Priority Date Claimed</p> <p><u>15</u> <u>October</u> <u>1998</u></p> <p>Day MONTH Year</p> <p>(use item 2 if no earlier priority)</p> |
|--|---|---|

4. Measured from the earliest priority date in item 3, this PCT/USA National Phase Application Request is being filed within:

(a) ☐ 20 months from above item 3 date (b) ☒ 30 months from above item 3 date,

(c) Therefore, the due date (unextendable) is : April 15, 2001

Title of Invention **METHOD AND SUBSTANCES FOR DIAGNOSIS AND THERAPY OF SEPSIS AND SEPSIS-LIKE SYSTEMIC INFECTIONS**

Inventor(s) BERGMANN, Andreas et al

Applicant herewith submits the following under 35 U.S.C. 371 to effect filing:

- ☒ Please immediately start national examination procedures (35 U.S.C. 371 (f)).
- ☐ **A copy of the International Application** as filed (35 U.S.C. 371(c)(2)) is transmitted herewith (file if in English but, if in foreign language, file only if not transmitted to PTO by the International Bureau) including:
- a. ☐ Request;
- b. ☐ Abstract;
- c. _____ pgs. Spec. and Claims;
- d. _____ sheet(s) Drawing which are ☐ informal ☐ formal of size ☐ A4 ☐ 11"

9. ☒ **A copy of the International Application has been transmitted by the International Bureau.**
10. **A translation of the International Application** into English (35 U.S.C. 371(c)(2))
- a. ☒ is transmitted herewith including: (1) ☐ Request; (2) ☒ Abstract;
(3) 24 pgs. Spec. and Claims;
(4) 10 sheet(s) Drawing which are:
☐ informal ☒ formal of size ☒ A4 ☐ 11"
- b. ☐ is not required, as the application was filed in English.
- c. ☐ is not herewith, but will be filed when required by the forthcoming PTO Missing Requirements Notice per Rule 494(c) if box 4(a) is X'd or Rule 495(c) if box 4(b) is X'd.
- d. ☐ Translation verification attached (not required now).

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11. ☒ Please see the attached Preliminary Amendment
12. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)), i.e., before 18th month from first priority date above in item 3, are transmitted herewith (file only if in English) including:
13. ☒ PCT Article 19 claim amendments (if any) have been transmitted by the International Bureau
14. ☐ Translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)), i.e., of claim amendments made before 18th month, is attached (required by 20th month from the date in item 3 if box 4(a) above is X'd, or 30th month if box 4(b) is X'd, or else amendments will be considered canceled).
15. **A declaration of the inventor** (35 U.S.C. 371(c)(4))
a. ☐ is submitted herewith ☐ Original ☐ Facsimile/Copy
b. ☒ is not herewith, but will be filed when required by the forthcoming PTO Missing Requirements Notice per Rule 494(c) if box 4(a) is X'd or Rule 495(c) if box 4(b) is X'd.
16. **An International Search Report (ISR):**
a. Was prepared by ☒ European Patent Office ☐ Japanese Patent Office ☐ Other
b. ☒ has been transmitted by the international Bureau to PTO.
c. ☒ copy herewith (5 pg(s).) ☒ plus Annex of family members (1 pg(s).).
17. **International Preliminary Examination Report (IPER):**
a. ☒ has been transmitted (if this letter is filed after 28 months from date in item 3) in English by the International Bureau with Annexes (if any) in original language.
b. ☐ copy herewith in English.
c.1 ☐ IPER Annex(es) in original language ("Annexes" are amendments made to claims/spec/drawings during Examination) including attached amended:
c.2 ☐ Specification/claim pages # _____ claims # _____
Dwg Sheets # _____
d. ☐ Translation of Annex(es) to IPER (required by 30th month due date, or else annexed amendments will be considered canceled).
18. **Information Disclosure Statement** including:
a. ☒ Attached Form PTO-1449 listing documents
b. ☒ Attached copies of documents listed on Form PTO-1449
c. ☒ A concise explanation of relevance of ISR references is given in the ISR.
19. ☐ **Assignment** document and Cover Sheet for recording are attached. Please mail the recorded assignment document back to the person whose signature, name and address appear at the end of this letter.
20. ☐ Copy of Power to IA agent.
21. ☐ **Drawings** (complete only if 8d or 10a(4) not completed): _____ sheet(s) per set: ☐ 1 set informal;
☐ Formal of size ☐ A4 ☐ 11"
22. Small Entity Status ☐ is **Not** claimed ☒ is claimed (pre-filing confirmation required)
22(a). _____ (No.) Small Entity Statement(s) enclosed (since 9/8/00 Small Entity Statements(s) not essential to make claim)
23. **Priority** is hereby claimed under 35 U.S.C. 119/365 based on the priority claim and the certified copy, both filed in the International Application during the international stage based on the filing in (country) GERMANY of:

Application No.		Filing Date		Application No.		Filing Date	
(1)	198 47 690.6	October 15, 1998	(2)	_____	_____		
(3)	_____	_____	(4)	_____	_____		
(5)	_____	_____	(6)	_____	_____		

a. ☒ See Form PCT/IB/304 sent to US/DO with copy of priority documents. If copy has not been received, please proceed promptly to obtain same from the IB.
b. ☐ Copy of Form PCT/IB/304 attached.

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24. Attached:

25 Per Item 17.c.2, cancel original pages # _____, claims # _____, Drawing Sheets # _____26. **Calculation of the U.S. National Fee (35 U.S.C. 371 (c)(1)) and other fees is as follows:**
Based on amended claim(s) per above item(s) ☐ 12, ☐ 14, ☐ 17, ☐ 25 (hilit)

Total Effective Claims	minus 20 =	x \$18/\$9	= \$0	966/967
Independent Claims	minus 3 =	x \$80/\$40	= \$0	964/965
If any proper (ignore improper) Multiple Dependent claim is present,		add \$270/\$135	+0	968/969

BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(4)): → → BASIC FEE REQUIRED, NOW → → → →

A. If country code letters in item 1 are not "US", "BR", "BB", "TT", "MX", "IL", "NZ", "IN" or "ZA"

See item 16 re:

1. Search Report was <u>not</u> prepared by EPO or JPO -----	add \$1000/\$500	960/961
2. Search Report was prepared by EPO or JPO -----	add \$860/\$430	970/971
	<u>+430</u>	

SKIP B, C, D AND E UNLESS country code letters in item 1 are "US", "BR", "BB", "TT", "MX", "IL", "NZ", "IN" or "ZA"

→ <input type="checkbox"/> B. If <u>USPTO</u> did not issue <u>both</u> International Search Report (ISR) and (if box 4(b) above is X'd) the International Examination Report (IPER), -----	add \$970/\$485	+0	960/961
→ <input type="checkbox"/> C. If <u>USPTO</u> issued ISR but not IPER (or box 4(a) above is X'd), -----	add \$710/\$355	+0	958/959
→ <input type="checkbox"/> D. If <u>USPTO</u> issued IPER but IPER Sec. V boxes <u>not all</u> 3 YES, -----	add \$690/\$345	+0	956/957
→ <input type="checkbox"/> E. If international preliminary examination fee was paid to <u>USPTO</u> and Rules 492(a)(4) and 496(b) <u>satisfied</u> (IPER Sec. V <u>all</u> 3 boxes YES for <u>all</u> claims), -----	add \$100/\$50	+0	962/963
	SUBTOTAL =	<u>\$430</u>	
28. If Assignment box 19 above is X'd, add Assignment Recording fee of ----\$40		+0	(581)
29. Attached is a check to cover the -----	TOTAL FEES	<u>\$430</u>	

Our Deposit Account No. 03-3975

Our Order No. 11377 | 279277
C# M#

00909

CHARGE STATEMENT: The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 and 492 (missing or insufficient fee only) now or hereafter relative to this application and the resulting Official document under Rule 20, or credit any overpayment, to our Account/Order Nos. shown above for which purpose a duplicate copy of this sheet is attached.

This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal form is filed

Pillsbury Winthrop LLP
Intellectual Property Group

By Atty: Paul N. Kokulis

Sig:

Reg. No. 16773

Fax: (202) 822-0944
Tel: (202) 861-3503

Atty/Sec: PNK/mhn

NOTE: File in duplicate with 2 postcard receipts (PAT-103) & attachments.

Inventor(s): BERGMANN ET AL (Atty. Dkt.
Appln. No.: 09/806,437 or Patent No.: 279277/2892 USAS/VO
Filed: March 30, 2001 or Issued.: M# / Client Ref.
Title: METHOD AND SUBSTANCES FOR DIAGNOSIS AND THERAPY OF SEPSIS AND SEPSIS-LIKE SYSTEMIC INFECTIONS
SMALL ENTITY STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(d) and 1.27 (c)) - SMALL BUSINESS CONCERN

I hereby state that I am

- ☐ the owner of the small business concern identified below: .
☒ an official of the small business concern empowered to act on behalf of the concern identified below:
NAME OF CONCERN B.R.A.H.M.S DIAGNOSTICA GMBH
ADDRESS OF CONCERN Neuendorfstrasse 25, 16761 Hennigsdorf, Germany

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I her by state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention **entitled: METHOD AND SUBSTANCES FOR DIAGNOSIS AND THERAPY OF SEPSIS AND SEPSIS-LIKE SYSTEMIC INFECTIONS**
by inventor(s) Bergmann et al described in

- ☒ x → ☐ the specification filed herewith,
☒ one → ☒ Application No. 09/806,437, filed March 30, 2001
☒ box → ☐ Patent No. _____, issued

If the rights held by the above identified small business concern are not exclusive, each small entity individual, concern or organization having rights to the invention is listed in (A) and (B) below and no rights to the invention are held by any person, other than the inventor, who could not qualify under 37 CFR 1.9(c) as an independent inventor if that person had made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

- (A) FULL NAME of assignee/licensee/grantee/conveyee*
ADDRESS
☐ INDIVIDUAL ☒ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION
- (B) FULL NAME of assignee/licensee/grantee/conveyee*
ADDRESS
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

*NOTE: Separate statement is required from each person, concern or organization named in (A) and (B) above having rights to the invention, averring to his/her/its status as a small entity. (37 CFR 1.27)

I acknowledge the duty to file, in this case, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Dr. Andreas Bergmann
TITLE OF PERSON OTHER THAN OWNER Vice President
ADDRESS OF PERSON SIGNING 10 BRAHMS Diagnostica, Neuendorfstr. 25, 16761 Hennigsdorf
SIGNATURE [Signature] DATE April 20, 2001